NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEANNA LEWAKOWSKI, *individually and on behalf of all other similarly situated*, Plaintiffs, v. **AQUESTIVE THERAPEUTICS, INC., *et al.***, Defendants.	Civil Action No. 21-3751 (ZNQ) (DEA) **OPINION**

QURAISHI, District Judge

THIS MATTER comes before the Court upon a Motion to Dismiss the Amended Complaint and strike certain allegations therein filed by Defendants Aquestive Therapeutics, Inc. ("Aquestive" or the "Company"), Keith J. Kendall, John T. Maxwell and Daniel Barber (the "Individual Defendants," and together, the "Defendants"). ("Motion", ECF No. 33.) Defendants filed a Brief in support of their Motion. ("Moving Br.", ECF No. 33-1.) Plaintiffs filed an Opposition to the Motion ("Opp'n Br.", ECF No. 34) to which Defendants replied ("Reply", ECF No. 36.)

The Court has carefully considered the parties' submissions and decides the Motion without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court will GRANT Defendants' Motion to Dismiss without prejudice and DENY Defendants' Motion to strike.

I. BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs initiated this action by filing their initial Complaint on March 1, 2021. (ECF No. 1.) On June 25, 2021, Plaintiffs filed an Amended Complaint—the operative Complaint at this stage. ("Am. Compl.", ECF No. 25.) This is a class action brought on behalf of a proposed class of all persons who purchased Aquestive common stock between August 7, 2019 and September 25, 2020, both dates inclusive ("Class Period"), and who were damaged thereby, pursuing remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder. (Am. Compl. ¶ 1.) The Complaint alleges that "Aquestive's future depends on a drug, Libervant, which uses the active pharmaceutical ingredient diazepam to treat epileptic cluster seizures." (*Id.* ¶ 2.) Aquestive seeks Libervant's Food and Drug Administration ("FDA") approval through a statutory provision that requires a showing that it is equivalent to the existing diazepam-based treatment, Diastat.[1] (*Id.*) Aquestive argued that the studies it had conducted were sufficient to file Libervant's New Drug Application ("NDA"), at which point the FDA asked Aquestive to conduct one last study measuring whether patients achieved the same diazepam blood concentration after receiving Libervant as after they received Diastat in real-world conditions. (*Id.*) This "Crossover Study" would compare differences in the absorption of diazepam in patients who had just eaten. (*Id.* ¶ 66.) "The results were troubling: 18% of patients reached peak bloodstream diazepam concentrations (a key metric) of only 50% as much under Libervant as they achieved under Diastat." (*Id.* ¶ 2.) Although this disparity existed, Defendants nevertheless consistently and recklessly "told investors that the study was an unqualified success and that there were no 'low responders'" beginning August 2019. (*Id.*) In

[1] As the Amended Complaint alleges, "Defendants sought approval via Section 505(b)(2) of the Food, Drug, and Cosmetic Act." (Am. Compl. ¶ 5) This mechanism is colloquially known as a "Paper NDA," which is distinct from an Abbreviated New Drug Application under FDCA Section 505(j).

September 2020, Defendants announced that the FDA had rejected Libervant's NDA because 18% of patients were low responders, causing Aquestive's stock price to fall by 34% in one day. (*Id.*) This was directly caused by Defendants' fraudulent conduct in feigning the drug's efficacy, assuring investors that the drug met all its goals in the FDA study. (*Id.* ¶¶ 88–101.)

To the extent that Defendants made fraudulent statements, Plaintiffs point to Defendant Barber's statement to investors regarding Libervant's data that "the [pre-NDA meeting] was a very positive meeting. There were a lot of elements of our program that were validated in that meeting, including the safety work we've done, including all of the Pharmacokinetics ("PK") work we've done to-date" (*id.* ¶ 79) and that "from our perspective, the FDA gave us verbal indication that we are very, very close and this is the end of the process" (*id.* ¶ 81). Plaintiffs also point to Defendant Kendall's assertion that Aquestive needed only to complete one additional study: "[t]he one piece of PK bridging data we have not collected to date is Diastat data in patients under conditions of use. We will conduct a small, single-dose, crossover study versus our Libervant in order to obtain this data." (*Id.* ¶ 80.) Defendants thereafter allegedly misconstrued the results of the study which ultimately misled investors. (*Id.* ¶ 92.) For example, Defendant Kendall stated

> We believe that we've met the specific requirements for approval communicated to us by the FDA. . . . Top line results confirmed our dosing model algorithm is appropriate for patients and will support a lower top dose than the top dose for the rectal gel. The results also show no difference between the film and the gel in patients using concurrent [anti-epileptic] medications. In addition, once again, we observed several patients in the study who did not respond to a dose of the rectal gel, but in those same patients, we were able to produce therapeutic blood levels with Libervant.

(*Id.* ¶ 91.) According to Plaintiffs, these statements were misleading because: (a) five of twenty-eight patients achieved peak concentration under Libervant that were only about 50% what they achieved under Diastat and, as a result, (i) there were "low responders" to Libervant, (ii) there were differences in overall diazepam exposure between Libervant and Diastat for patients on anti-

epileptic drugs ("AEDs") because all patients were on AEDs, (iii) these same five patients showed a "difference between the film and the gel in patients using concurrent AED medications", and (iv) the concentration of diazepam was not relatively consistent between patients; and (b) Defendants knew or were reckless in not knowing that Aquestive had not met the specific requirements the FDA communicated. (*Id.* ¶ 92.) Consequently, Plaintiffs allege two Counts: violation of section 10(b) of the Exchange Act and Rule 10b-5 (Count I) and violation of section 20(a) of the Exchange Act (Count II).

On August 16, 2021, Defendants filed their Motion to Dismiss and Motion to Strike Allegations in the Amended Complaint. (ECF No. 33.)

II. LEGAL STANDARD

A. RULE 12(b)(6)

Under Fed. R. Civ. P. 12(b)(6), a complaint may be dismissed for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (quotations omitted). Under such a standard, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Indeed, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[A] complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009).

However, Rule 12(b)(6) only requires a "short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. The complaint must include "enough factual matter (taken as true) to suggest the required element. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips*, 515 F.3d at 234 (citation and quotations omitted); *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim. The pleading standard is not akin to a probability requirement; to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citation and quotations omitted)).

In sum, under the current pleading regime, when a court considers a dismissal motion, three sequential steps must be taken: first, "it must take note of the elements the plaintiff must plead to state a claim." *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quotations omitted). Next, the court "should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id*. (quotations omitted). Lastly, "when there are well-pleaded factual allegations, the court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id*. (quotations and brackets omitted).

B. RULE 9

"Independent of the standard applicable to Rule 12(b)(6) motions," Fed. R. Civ. P. 9(b) "imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud." *In re Rockefeller Ctr. Props. Secs. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002); *see also* Fed.

R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."). To satisfy this heightened pleading standard, a plaintiff must state the circumstances of his alleged cause of action with "sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank of America*, 361 F.3d 217, 223-24 (3d Cir. 2004)). Specifically, the plaintiff must plead or allege the "date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico*, 507 F.3d at 200 (citing *Lum*, 361 F.3d at 224). Indeed, the Third Circuit has advised that, at a minimum, Rule 9(b) requires a plaintiff to allege the "essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276-77 (3d Cir. 2006) (quoting *In re Rockefeller*, 311 F.3d at 216).

C. THE PSLRA

In addition to Rule 9(b)'s heightened pleading requirements, Congress enacted the PSLRA, 15 U.S.C § 78u, *et seq.*, to require an even higher pleading standard for plaintiffs bringing private securities fraud actions. *In re Suprema*, 438 F.3d at 276. This heightened pleading standard is targeted at preventing abusive securities litigation. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) ("Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law."); *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006) (identifying "ways in which the class-action device was being used to injure the entire U.S. economy" and listing examples such as "nuisance filings, targeting of deep-pocket

defendants, vexatious discovery requests, and manipulation by class action lawyers of the clients whom they purportedly represent . . . .") (quotes and citations omitted).

The PSLRA provides two distinct pleading requirements, both of which must be met in order for a complaint to survive a motion to dismiss. *Institutional Investors Group v. Avaya, Inc*., 564 F.3d 242, 252 (3d Cir. 2009). First, under 15 U.S.C. § 78u–4(b)(1), the complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Winer Family Trust v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007) (construing 15 U.S.C. § 78u–4(b)(1)). Second, the complaint must, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2).

Both provisions of the PSLRA require facts to be pled with "particularity." *Avaya*, 564 F.3d at 253. This particularity language "echoes precisely Fed. R. Civ. P. 9(b)." *In re Advanta Corp. Sec. Litig*., 180 F.3d 525, 534 (3d Cir. 1999); *see* Fed. R. Civ. P. 9(b) ("[A] party must state with particularity the circumstances constituting fraud or mistake."). Indeed, although the PSLRA replaces Rule 9(b) as the pleading standard governing private securities class actions, the rule's particularity requirement "is comparable to and effectively subsumed by the requirements of [§ 78u–4(b)(1) of] the PSLRA." *Avaya*, 564 F.3d at 253 (citations omitted). This standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *In re Advanta*, 180 F.3d at 534 (quotations marks omitted).

III. DISCUSSION

A. MOTION TO DISMISS: SECTION 10(B) OF THE EXCHANGE ACT

The private right of action under Section 10(b) and Rule 10b–5 "creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market." *In re Burlington Coat Factory Sec. Litig*, 114 F.3d 1410, 1417 (3d Cir. 1997). In relevant part, Rule 10b–5 makes it unlawful for an individual "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5(b). To state a claim under Section 10(b) of the Exchange Act and Rule 10b–5, the plaintiff must allege: "(1) a material misrepresentation or omission, (2) scienter, (3) a connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation." *Gold v. Ford Motor Co*., 577 F. App'x 120, 122 (3d Cir. 2014) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005)).

Here, Defendants argue, among other things, that Plaintiffs fail to state a claim for securities fraud because: (a) Plaintiffs fail to plead any actionable misstatement or omission[2] (Moving Br. at 20); and (b) Plaintiffs fail to plead a strong inference of scienter (*id.* at 32).

1. Material Misrepresentation or Omission

Under Section 10(b) and Rule 10b–5, a misrepresentation or omission of fact is material "if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision, and there is a "substantial likelihood that the disclosure of the

[2] Specifically, Defendants argue that Plaintiffs fail to plead that statements regarding the crossover study were false and misleading (Moving Br. at 20), statements regarding the regulatory path forward and likelihood of FDA approval are forward-looking and therefore nonactionable (*id.* at 27), and Defendants' statements of belief regarding the crossover study and FDA approval are nonactionable under *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015) (*id.* at 29).

omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus. v. Northway*, 426 U.S. 438, 440 (1976)); *see also Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000). Importantly, to be actionable, a statement or omission must have been materially misleading at the time it was made; liability cannot be imposed on the basis of subsequent events. *In re NAHC, Inc. Sec. Litig*., 306 F.3d 1314, 1330 (3d Cir. 2002).

Additionally, because materiality is a mixed question of law and fact, "[o]nly if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality is it appropriate for the district court to rule that the allegations are inactionable as a matter of law." *Shapiro v. UJB Financial Corp*., 964 F.2d 272, 280 n.11 (3d Cir. 1992) (citation omitted). The Third Circuit has warned that the task of determining materiality can be especially difficult when the statement at issue contains "soft" information, i.e., statements of subjective analysis or extrapolation, such as opinions, motives, and intentions, or forward-looking statements, such as projections, estimates, and forecasts. *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 642 (3d Cir. 1989).

However, regardless of whether a piece of information is material, Section 10(b) and Rule 10b–5 "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Indeed, "[s]ilence, absent a duty to disclose, is not misleading under Rule 10b–5." *City of Edinburgh Council v. Pfizer, Inc*., 754 F.3d 159, 174 (3d Cir. 2014) (quoting *Basic*, 485 U.S. at 239 n.17). Rather, "[d]isclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)); *see*

also City of Edinburgh, 754 F.3d at 174; *Burlington*, 114 F.3d at 1432 (3d Cir. 1997) ("[P]ossession of material nonpublic information alone does not create a duty to disclose it.").

Additionally, according to the Supreme Court's decision in *Omnicare*, when the alleged misleading statement at issue is an opinion or a belief, whether that statement is 'misleading' "depends on the perspective of a reasonable investor: The inquiry (like the one into materiality) is objective." 575 U.S. at 187. Although *Omnicare* examined claims under Section 11 of the Securities Act of 1933, these principles are "not unique to § 11." *Id*. at 191. Rather, "[t]hey inhere, too, in much common law respecting the tort of misrepresentation," *id*., and are therefore arguably applicable to claims under Section 10(b) as well. *See In re Merck & Co*., Civ. No. 05-1151, 2015 WL 2250472, at *9 (D.N.J. May 13, 2015) (finding *Omnicare*'s analysis of misleading opinions instructive, to some extent, on the viability of claims regarding misleading opinions under Section 10(b)).

As the Supreme Court observed:

> The Restatement of Torts, for example, recognizes that '[a] statement of opinion as to facts not disclosed and not otherwise known to the recipient may' in some circumstances reasonably 'be interpreted by him as an implied statement' that the speaker 'knows facts sufficient to justify him in forming' the opinion, or that he at least knows no facts 'incompatible with [the] opinion.' When that is so, the Restatement explains, liability may result from omission of facts—for example, the fact that the speaker failed to conduct any investigation—that rebut the recipient's predictable inference.

Omnicare, 135 U.S. at 191 (quoting Restatement (Second) of Torts § 539 at 85, Comment a at 86, Comment b at 87 (1976) (citations omitted)). These principles are consistent with the Third Circuit's admonition that when evaluating Section 10(b) claims, courts must examine allegedly misleading statements in context, to determine whether they were indeed misleading. *See City of Edinburgh*, 754 F.3d at 167. Furthermore, the Third Circuit has deemed determinative that

"[o]pinions are only actionable under securities laws [including Section 10(b),] if they are not honestly believed and lack a reasonable basis." *Id*. at 170.

Similarly, under the PSLRA, "forward-looking" statements are not actionable if they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna Sec. Litig*., 617 F.3d 272, 278–79 (3d Cir. 2010). The PSLRA's definition of "forward-looking statement" includes, inter alia, "projections of future performance, plans and objectives for future operations, and assumptions underlying statements about future financial, economic or operational performance." *Id*. at 279 (citing 15 U.S.C. § 78u–5(i)(1)). This safe harbor for forward-looking statements overlaps with the Third Circuit's "bespeaks caution" doctrine, adopted in *In re Donald J. Trump Casino Sec. Litig*., 7 F.3d 357 (3d Cir. 1993). Under this doctrine, "cautionary language, if sufficient, renders the alleged [forward-looking] omissions or misrepresentations immaterial as a matter of law." *Id*. at 371. Under both the PSLRA and the bespeaks caution doctrine, cautionary language must be extensive, specific, and directly related to the alleged misrepresentation to provide a safe harbor. *See In re Aetna*, 617 F.3d at 282; *Id*. at 371–72.

In addition, like forward-looking statements, opinions, and beliefs, a defendant may not be held liable for an alleged misrepresentation that consists of nothing more than vague and nonspecific expressions of corporate optimism. *In re Advanta*, 180 F.3d at 538. Such statements "constitute no more than 'puffery' and are understood by reasonable investors as such." *Id*. (quoting *Burlington*, 114 F.3d at 1428 n.14). Thus, if a false or misleading statement is "too vague to ascertain anything on which a reasonable investor might rely," it is inactionable as corporate puffery. *In re Aetna*, 617 F.3d at 284.

Here, Defendants argue that Plaintiffs have failed to state a claim because, pursuant to the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Plaintiffs are required to "meet the high burden of pleading with particularity 'each statement alleged to have been misleading, [and] the reason . . . why the statement is misleading,' as well as 'particulari[zed] facts giving rise to a strong inference' that each defendant acted with scienter." (Moving Br. at 1–2.) Specifically, Plaintiffs fail to plead a material misstatement or omission and instead "cherry-pick out-of-context quotes from the Company's disclosures." (*Id.* at 5.) Plaintiffs' claims also independently fail because "they have not alleged particularized facts evincing a strong inference of scienter that is cogent and at least as compelling as any non-fraudulent inference." (*Id.*) Contrary to Plaintiffs' allegations, Aquestive actually warned its investors that it might not obtain FDA approval. (*Id.* at 14.) Moreover, Aquestive's forward-looking statements are nonactionable because they were accompanied by meaningful cautionary statements. (*Id.* at 27.) Furthermore, the statements of belief by Defendants Kendall and Maxwell regarding the Crossover Study results and Libervant's prospects of FDA approval are not actionable because these were "sincere statements of pure opinion." (*Id.* at 30.) Lastly, Plaintiffs failed to plead a strong inference of scienter because they did not plead any motive or conscious disregard with respect to Defendants' statements. (*Id.* at 32–36.) "Unable to plead particularized facts to show that Defendants made material misstatements with scienter, Plaintiffs devote no fewer than 40 paragraphs of the [Amended Complaint] to recounting unproven and unadjudicated allegations from preliminary proceedings in two unrelated civil actions." (*Id.* at 38.) Accordingly, Defendants argue that the Court should strike Plaintiffs' allegations regarding Suboxone, a different drug not at issue here (Am Compl. ¶¶ 27–36) and the numerous unadjudicated allegations asserted by one of Aquestive's direct competitors, Neurelis (*id.* ¶¶ 49, 106–134).

Plaintiffs, on the other hand, contend that Defendants misled investors by making statements concerning (a) the results of the Crossover study (Am. Compl. ¶¶ 89, 94–95); and (b) Libervant's prospects for FDA approval (*id*. ¶¶ 91, 96–97, 99). The Court will assess each set of allegedly false and misleading statements, in turn.

a) Statements Concerning the Crossover Study

Plaintiffs allege Defendants falsely assured investors that the Crossover study had met all it goals. According to Plaintiffs, "on August 6, 2019, Defendants issued one press release announcing Q2 2019 ('Q2 2019 PR') financial results and another announcing the results of the Crossover study ('Study Results PR')." (Am. Compl. ¶ 88.) In the Q2 2019 PR, Defendants stated:

> The Company reported positive topline data from the single dose crossover study, which compared the pharmacokinetic responses in a common set of patients receiving a dose of Libervant™ (diazepam) Buccal Film and a dose of diazepam rectal gel. Preliminary analyses show that the overall diazepam exposure achieved from the buccal film was the same as for gel based on the patient dosing algorithm and there was no difference between buccal film and gel in the effect of enzyme induction from taking concurrent anti-epileptic medications. **Additionally, there were no instances of low or non-responders observed after Libervant administration**, while over 10% of those same patients failed to achieve adequate exposure following gel administration.

(*Id.* ¶ 89) (bold in original). In the Study Results PR, Defendants stated: "among the 28 patients valid for analysis, three patients (10.7%) failed to achieve therapeutic concentrations of diazepam when using rectal gel. **There were no such failures following buccal film administration**." (*Id.* ¶ 90) (bold in original). Then, on August 7, Defendants held a conference call to discuss both Q2 2019 earnings and the results of the Crossover Study, at which point Defendant Kendall stated in prepared remarks:

> We believe that we've met the specific requirements for approval communicated to us by the FDA. Top line results confirmed our

> dosing model algorithm is appropriate for patients and will support a lower top dose than the top dose for the rectal gel. The results also show no difference between the film and the gel in patients using concurrent AED medications. In addition, once again, we observed several patients in the study who did not respond to a dose of the rectal gel, but in those same patients, we were able to produce therapeutic blood levels with Libervant.

(*Id.* ¶ 91)(emphasis omitted.) Plaintiffs reason that these statements are actionable because:

> (a) five of twenty-eight patients achieved peak concentration under Libervant that were only about 50% what they achieved under Diastat and, as a result, (i) there were "low responders" to Libervant, (ii) there were differences in overall diazepam exposure between Libervant and Diastat for patients on AEDs because all patients were on AEDs, (iii) these same five patients showed a "difference between the film and the gel in patients using concurrent AED medications", and (iv) the concentration of diazepam was not relatively consistent between patients; (b) Defendants knew or were reckless in not knowing that Aquestive had not met the specific requirements the FDA communicated; and, as a result, (c) Defendants' statements gave the misleading impression that the Crossover Study had met all its goals.

(*Id.* ¶ 92.)

Defendants counter that "the term 'low or non-responders' does not refer to some undefined 'low' concentration of diazepam as compared to Diastat, as Plaintiffs suggest. Rather, it is defined precisely and objectively as patients who failed to achieve an absolute level of diazepam exposure—i.e., patients with a blood concentration of diazepam below 'the 70 nanogram per ml ("ng/mL") plasma concentration that [Aquestive] had discerned as being therapeutic' in prior studies." (Moving Br. at 13, 21; Def. Ex. G, 2019 8-k, at 11; Def. Ex. H, Shareholder Tr., at 11.) In that context, Defendants maintain that the Company made clear every patient who received Libervant in the Crossover Study achieved a level of diazepam that exceeded this threshold, even though a number of Diastat patients failed to exceed that level. (*Id.*; *Id.*)

When examined in its full context, it is evident to the Court that Defendants disclosed that "low or non-responders" was with regard to the 70 ng/mL plasma concentration that Aquestive

had discerned as being therapeutic in prior studies. *In re Newell Brands, Inc. Sec. Litig.*, Civ. No. 18-10878, 2019 WL 6715055, at *11 (D.N.J. Dec. 10, 2019) ("[C]ourts must 'examine statements in the full context . . . and not engage in a 'selective reading'"), *aff'd*, 837 F. App'x 869 (3d Cir. 2020). To the extent that Plaintiffs challenge Defendants' opinion that 70 ng/mL plasma concentration was therapeutic, as the Court noted above, the Third Circuit has deemed determinative that "[o]pinions are only actionable under securities laws [including Section 10(b),] if they are not honestly believed and lack a reasonable basis." *City of Edinburgh*, 754 F.3d at 170. Here, Plaintiffs do not challenge Defendants' basis for their opinion that 70 ng/mL plasma concentration is enough to be therapeutic or their honest belief in that opinion.

Plaintiffs similarly mischaracterize Defendant Maxwell's remark that "every single time we dose, in the studies that we've done, we've gotten the blood levels that we need in a clinical study." (Am. Compl. ¶¶ 94, 99). As the full transcript confirms, Maxwell's reference to "blood levels that we need in a clinical study" plainly refers to the precisely defined therapeutic threshold of 70 ng/mL, for which patients had a "100% response rate" using Libervant. (Def. Ex. Y, Conference Tr., at 4.) Taken in its full context, it is clear that Defendants are not making a blanket statement comparing Libervant's study results to Diastat, but instead are opining as to what would be a sufficient plasma concentration: 70 ng/mL.

Next, Plaintiffs challenge Defendants' statements interpreting the Study's topline results, including: (1) "[t]he Company reported positive topline data from the single dose crossover study"; (2) "the overall diazepam exposure achieved from the buccal film was the same as for gel based on the patient dosing algorithm"; and (3) "[t]opline results confirmed our dosing model algorithm is appropriate for patients" and "also show no difference between the film and the gel in patients using concurrent AED medications." (Am. Compl. ¶¶ 89, 91.) Plaintiffs allege these statements

were false based solely on the FDA's conclusion that certain specific weight groups and individual patients achieved lower than desired concentrations of diazepam. (*Id.* ¶ 100.) This characterization, however, does not render false the Company's interpretations of the overall results of the Crossover Study, which the FDA agreed showed "comparable" overall absorption levels for Libervant. (Def. Ex. U, 2020 8-K, at 7, 10, ECF No. 33-23.) In a similar context of sharing topline results, Courts "have noted that '[i]nterpretations of clinical trial data are considered opinions [and o]pinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *In re Amarin Corp. PLC Sec. Litig.*, Civ. No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022) (quoting *City of Edinburgh*, 754 F.3d at 170)).

Nothing in the record suggests, nor do Plaintiffs allege, that the topline results were not honestly believed and lacked a reasonable basis in light of the FDA's finding that Libervant in fact "achieved comparable absorption rates when compared to Diastat." (Def. Ex. U, 2020 8-K, at 10.) Plaintiffs' claims are further insufficient because the underlying weight-group-level data was publicly disclosed during the Class Period. (Def. Ex. M, Dec. 2019 AES Poster, ECF No. 30-15.) Although the FDA ultimately determined that Cmax levels for certain weight groups were "too low," the FDA's difference of opinion in interpreting the data cannot support a securities fraud claim. *City of Edinburgh*, 754 F.3d at 170 (affirming dismissal of 10(b) claims because "disagreement[s] . . . with the company's interpretation of the interim results is not sufficient to show defendants' interpretation lacked a reasonable basis."); *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013) ("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement."). The Court therefore concludes that the Complaint fails to plead a false or misleading statement of opinion because it does not plausibly

allege that the topline results announced by Defendants were not honestly believed and lacked a reasonable basis.

Rather than "the misleading impression that the Crossover Study was an unqualified success" (Am. Compl. ¶ 100.), Aquestive repeatedly warned investors of the difficulties associated with obtaining FDA approval. Aquestive disclosed that the 505(b)(2) pathway is "inherently uncertain" (Def. Ex. O, 2018 S-1, at 34), "many companies . . . believe[] their product candidates performed satisfactorily in preclinical studies and clinical trials [but] nonetheless fail[] to obtain FDA approval," (Def. Ex. C, 2020 10-K, at 35, ECF No. 33-5; Def. Ex. E, 2019 10-K, at 34, ECF No. 33-7 ; Def. Ex. P, 2021 10-K, at 28, ECF No. 33-18), these statements "are subject to a number of risks and uncertainties . . . [including] . . . risk of delays in FDA approval of Libervant . . . or failure to receive approval . . ." (Ex. C, 2020 10-K, at 3) and "there can be no assurance that we will be successful in these [Libervant approval] efforts" (Def. Ex. Q, 2020 8-K, at 3; Def. Ex. C, 2020 10-K, at 36).

b) Statements Concerning the Prospect of FDA Approval

Plaintiffs also challenge statements regarding the future prospects of FDA approval, such as: (1) "We believe that we've met the specific requirements for approval communicated to us by the FDA"; (2) "We believe these results . . . satisfy the final clinical requirement requested by the FDA"; (3) "[W]e believe we've provided the FDA with all of the appropriate data in response to the questions they had"; and (4) "I think you'll agree we have the data required for approval to bring this highly differentiated product, Libervant, to market." (Am. Compl. ¶¶ 91, 97, 99.)

As noted above, under the PSLRA, "forward-looking" statements are not actionable if they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna Sec. Litig.*, 617 F.3d at 278–79. The term "'forward-looking statement' is broadly defined

in the [PSLRA] to include statements . . . of the plans and objectives of management for future operations, including plans or objectives relating to the products . . . of the issuer." *Avaya*, 564 F.3d at 255 (quoting § 78u-5(i)(1)(A)-(C)). Courts in this Circuit have interpreted this definition to include statements where "a defendant expresses the likelihood of approval by a regulatory agency" such as the FDA. *Hoey v. Insmed Inc.*, Civ. No. 16-4323, 2018 WL 902266, at *19 (D.N.J. Feb. 15, 2018); *see Eagle Pharms.*, 2017 WL 2213147, at *9; *see also Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016). Thus, statements that Aquestive believed it met the specific requirements for approval or would satisfy the FDA "clearly fall[] within the ambit of the PSLRA's safe-harbor" if they were forward-looking and accompanied by specific cautionary language. *Hoey*, 2018 WL 902266, at *19.

The Court concludes that each of the criteria for safe harbor are met. First, Defendants' statements were accompanied by specific warnings that disclosed specific risks, including that "even after successful completion of clinical testing [for any of our products], there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission." (Def. Ex. E, 2019 10-K at 34.) Second, Defendants' forward-looking statements are nonactionable because Plaintiffs "have not sufficiently pleaded a strong inference that defendants acted with actual knowledge that their projections were false or misleading." *Avaya, Inc.*, 564 F.3d at 259. "[T]he scienter requirement for forward-looking statements"—actual knowledge—"is stricter than for statements of current fact . . . [and] attaches only upon proof of knowing falsity." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 773 (2d Cir. 2010); *see also Intel Corp. Inv. Pol'y Comm. v. Sulyma*, 140 S. Ct. 768, 772 (2020) ("[T]o have 'actual knowledge' . . . one must in fact be aware of it."). Plaintiffs do not

allege any facts, particularized or otherwise, that Defendants actually knew their optimistic statements about FDA approval were false when made.

Most notably, the court in *Hoey* explained that a defendant's statement that he "saw an approvable drug, bottom line" at an investor conference was mere puffery because it clearly embodied the defendant's opinion and no reasonable investor would rely on that statement. 2018 WL 902266, at *18. Similarly here, Defendants' statements can be characterized as mere puffery. These allegations suffer from the same flaw in Plaintiffs' arguments throughout their Amended Complaint; in demonstrating falsity, Plaintiffs reference concerns that were raised after the fact. More to the point, a reasonable investor would not rely on these statements. Indeed, it clearly embodies the opinions of the defendants, and amounts to nothing more than a "gut feeling" stemming from optimistic views of their studies. *Id.* "Statements of this kind are a paradigm of corporate puffery, and, therefore, they cannot serve as the basis for § 10(b) liability." *Id.* (citing *Vallabhaneni v. Endocyte, Inc.*, Civ. No. 14-1048, 2016 WL 51260, at *15, (S.D. Ind. Jan. 4, 2016) ("Courts frequently consider loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker that no reasonable investor could find them important to the 'total mix of information available' to be immaterial as a matter of law." (internal citation omitted)); *Lopez v. CTPartners Exec. Search, Inc.*, 173 F. Supp. 3d 12, 28 (S.D.N.Y. 2016) (holding that statements which are "so broad and nebulous as to not provide any specific or concrete guarantee" are not relied on by reasonable investors); *In re Medimmune, Inc. Sec. Litig.*, 873 F.Supp. 953, 964 (D. Md. 1995) ("Mere expressions of hope or expectation regarding future approval, not worded as guarantees, are not actionable.")). Accordingly, Defendants' statements are forward-looking, accompanied by cautionary statements, immaterial to reasonable investors, and therefore not actionable.

c) Omnicare

Finally, the statements of belief by Defendants Kendall and Maxwell regarding the Crossover Study results and Libervant's prospects for FDA approval (Am. Compl. ¶¶ 89–91, 94, 96, 97, 99) independently fail under the Supreme Court's decision in *Omnicare*, 575 U.S. 175, under which "[a] sincere statement of pure opinion is not an 'untrue statement of material fact,' regardless of whether an investor can ultimately prove the belief wrong." *Id.* at 186. Rather, such a statement is actionable only if (1) "the speaker did not hold the belief she professed," (2) "the supporting facts she supplied were untrue," or (3) the speaker omits information "whose omission makes the statement misleading to a reasonable person reading the statement fairly and in context." *Id*. at 186, 194. Thus, meeting the *Omnicare* standard is "no small task" for securities plaintiffs. *Id*. at 194.

The Third Circuit has held that "[i]nterpretations of clinical trial data are considered opinions . . . [and] are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *Pfizer*, 754 F.3d at 170; *accord Hoey*, 2018 WL 902266, at *17. This is because "[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." *Gillis*, 197 F. Supp. 3d at 595 (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015)).

Plaintiffs fail to allege that Defendants Kendall or Maxwell did not honestly hold their beliefs and interpretations of the Study's results. Rather, "[a]t bottom, [p]laintiffs' allegations regarding [d]efendants' stated opinion about the [clinical] trial results are little more than a dispute about the proper interpretation of data, a dispute this Court rejected as a basis of liability." *Sanofi*, 816 F.3d at 214; *Gillis*, 197 F. Supp. 3d at 598. The challenged statements of belief by Kendall that the FDA was likely to approve the Libervant NDA (Am. Compl. ¶¶ 91, 96, 97, 99) fare no better. *See, e.g.*, *Sanofi*, 816 F.3d at 211 (applying *Omnicare* to claims "expressing optimism,

even exceptional optimism, about the likelihood of drug approval"); *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, Civ. No. 05-1151, 2015 WL 2250472, at *11 (D.N.J. May 13, 2015). Again, Plaintiffs do not allege that Kendall did not honestly hold this optimism, nor do they allege that the FDA gave him any reason to question his beliefs during the Class Period. *Amarin*, 689 F. App'x at 131 (affirming dismissal of securities claim where "the FDA remained open to [a company's] strategy of demonstrating efficacy"); *Gillis*, 197 F. Supp. 3d 557 at 588.

2. Scienter

Setting aside whether the statements cited by Plaintiffs are materially false or misleading, Plaintiffs have also failed to adequately plead that the Individual Defendants acted with scienter, an essential element of a claim for a Rule 10b–5 violation.

"Scienter" stands for the "mental state [of] intent to deceive, manipulate or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n. 12 (1976). Under this PSLRA's pleading requirement, a plaintiff must "'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Avaya*, 564 F.3d at 267 (quoting 15 U.S.C. § 78u–4(b)(2)). The scienter standard requires a plaintiff to allege facts giving rise to a "strong inference of "either reckless or conscious behavior." *Advanta*, 180 F.3d at 534–35. Courts must weigh the "plausible nonculpable explanations for the defendant's conduct" against the "inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 310. A "strong inference" of scienter is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id*. at 314; *see id*. at 324 ("The inference that the defendant acted with scienter need not be irrefutable, i.e., of the 'smoking-gun' genre, or even the most plausible of competing inferences" (internal quotation marks omitted)).

"[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences . . . . A plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference." *Tellabs*, 551 U.S. at 323–29. "While [courts] [ ] aggregate the allegations in the complaint to determine whether [they] create[ ] a strong inference of scienter, plaintiffs must create this inference with respect to each individual defendant in multiple defendant cases." *Winer Family Trust v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007) (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 603 (7th Cir. 2006)).

In alleging that the Individual Defendants acted with scienter, Plaintiffs plead the following: (1) Aquestive "push[ed] forward with Libervant's NDA after the Crossover Study's mixed results" because it "was Aquestive's only chance to beat its competitor to market" (Am. Compl. ¶¶ 104–36); (2) Defendants sought to inflate the value of Aquestive's stock price because Aquestive "needed cash they could only secure by selling stock" (*id.* ¶¶ 137–44); and (3) although Defendants "could not hope to secure FDA approval of Libervant," they nonetheless pushed ahead with the NDA knowing their purported scheme would be thwarted months later when the FDA issued its Complete Response Letter ("CRL") (*id.* ¶ 151). Although the Court will examine the totality of the inferences raised by Plaintiff, those pertaining to the Individual Defendants' motives and opportunities will be analyzed before allegations related to conscious misbehaviors or recklessness. *See Avaya*, 564 F.3d at 268.

a) Motive and Opportunity

While the Third Circuit recognizes that " 'motive and opportunity' may no longer serve as an independent route to scienter" in the wake of *Tellabs*'s instructions to consider the Complaint in its entirety, particularized allegations regarding motive and opportunity may, in combination with other allegations, support a strong inference of scienter. *Avaya*, 564 F.3d at 268; *see also*

Tellabs, 551 U.S. at 323–29. Motive must be supported by facts stated "with particularity"; "[b]lanket assertions of motive and opportunity" will not suffice, and "catch-all allegations that defendants stood to benefit from wrongdoing and had the opportunity to implement a fraudulent scheme are no longer sufficient." *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004).

Fatally, the Amended Complaint does not put forth any "particularized allegations of a concrete and personal benefit to the individual defendants resulting from the fraud," nor do Plaintiffs allege that any Defendant received a personal benefit through the sale of personally held Aquestive stock during the Class Period. *In re Bio-Tech. Gen. Corp. Sec. Litig.*, 380 F. Supp. 2d 574, 586-87 (D.N.J. 2005). Instead, the Amended Complaint makes three blanket assertions of motive that all rely on the assumption that Defendants engaged in securities fraud in order to obtain FDA approval for Libervant.

The court in *Hoey* addressed similar issues as those raised by Plaintiffs' first and third allegations here. In *Hoey,* the plaintiff averred "that the Individual Defendants, to continue operating, strived 'to maintain the illusion of positive phase 2 results,' such that they could raise capital for, and complete enrollment in, a [subsequent] Trial." 2018 WL 902266, at *21. *Hoey* however adopted the reasoning of the Fourth Circuit in *Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 627 (4th Cir. 2008), and rejected an identical argument holding that: "[i]t is improbable that [a pharmaceutical corporation] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure." *Hoey,* 2018 WL 902266, at *21. This reasoning is persuasive: either Aquestive, realized that it could not indefinitely maintain a false impression of the trial's results, or it truly believed that it would obtain FDA approval and thus proceeded forward, which would negate any inference of scienter. *See Gillis*, 197 F. Supp. 3d at 600

(rejecting "implausible" scienter theory because "by its nature, [defendants'] purported scheme could not have continued in perpetuity. Defendants would have known that their efforts [in] feigning likely FDA approval would be revealed, in relatively short order, upon the FDA's rejection"); *see also In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446-47 (S.D.N.Y. 2006) (recognizing "the tenuous plausibility of the [defendant's] alleged scheme" where the public would "quickly uncover the scheme").

Plaintiffs' second allegation falls short for the same reason. *See Avaya*, 564 F.3d at 278–79 ("a general corporate desire to retire debt and raise funds and obtain credit on favorable terms . . . fail[s] to contribute meaningfully to a 'strong inference' of scienter" because "motivations to raise capital . . . are common to every company"); *see also In re MELA Scis., Inc. Sec. Litig.*, Civ. No. 10-8774, 2012 WL 4466604, at *5 (S.D.N.Y. Sept. 19, 2012) (holding that defendant's "capital raise[] during the Class Period" is "inadequate to support an allegation of intent to commit fraud"). The Court in *Hoey* rejected similar arguments that the defendant had fraudulent motives to raise capital but held that the company's "secondary offering," "fail[ed] to support a strong inference of scienter." 2018 WL 902266, at *22 ("[b]ecause these allegations of motive are applicable to any corporation seeking to commercialize an investigational drug, [p]laintiffs have failed to adequately plead motive"); *see also, e.g.*, *Key Equity Invs., Inc. v. Sel-Leb Mktg. Inc.*, 2005 WL 3263865, at *6 (D.N.J. Nov. 30, 2005), *aff'd*, 246 F. App'x 780 (3d Cir. 2007). Similarly here, an offering of company stock is not indicative of scienter. Even more so, Plaintiffs do not allege that Defendants partook in insider trading by selling their stock in this allegedly doomed investment to effectuate this fraud. Although not determinative, courts have consistently weighed this fact against an inference of scienter. *See, e.g., In re Mela*, 2012 WL 4466604, at *5 ("[N]o defendant sold [the company's] shares … during the class period. This is inconsistent with an

intent to commit fraud."); *National Junior Baseball League v. PharmaNet Dev. Group, Inc.*, 720 F.Supp.2d 517, 558 (D.N.J. 2010) ("[T]he fact that [the individual defendants] did not sell any [of the company's] stock during the Class Period tends to negate scienter."); *Turner v. MagicJack VocalTec, Ltd.*, Civ. No. 13-0448, 2014 WL 406917, at *11 (S.D.N.Y. Feb. 3, 2014) ("That three of the four individual Defendants, all high-ranking executives at the Company, did not sell stock during the Class Period . . . rebuts an inference of scienter."); *In re N. Telecom Secs. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of stock sales by insiders . . . is inconsistent with an intent to defraud shareholders."). Accordingly, Defendants sufficiently pled that they were not intending to deceive the public by continuing to move forward with the NDA process, but instead honestly believed in the strength of Libervant in discussing its results.

b) Conscious Behavior or Recklessness

Next, the Court turns to Plaintiff's allegations of scienter concerning the Individual Defendants' alleged conscious misbehavior or recklessness. "The standard for 'conscious misbehavior or recklessness' requires misrepresentations to be 'so recklessly made that the culpability attaching to such reckless conduct closely approaches that which attaches to conscious deception.'" *In re Radian Sec. Litig.*, 612 F.Supp.2d 594, 622 (E.D. Pa. 2009) (quoting *In re Digital Island Sec. Litig.*, 357 F.3d 322, 332 (3d Cir. 2004)). "Conscious misbehavior involves 'intentional fraud or other deliberate illegal behavior.'" *In re Radian*, 612 F.Supp.2d at 613 (quoting *In re Advanta*, 180 F.3d at 535). Recklessness involves "not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *In re Advanta*, 180 F.3d at 539. "An important point about the substantive meaning of recklessness in the securities fraud context, namely, that—in a case involving inaccurate public statements—simply alleging that defendants 'knew or should

have known' is not enough and, 'where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information.'" *In re Intelligroup Sec. Litig.,* 527 F. Supp. 2d 262, 286 (D.N.J. 2007) (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)).

In the instant matter, Plaintiffs claim that Defendants either "knew or were reckless in not knowing that Aquestive had not met the specific requirements the FDA communicated." (Am. Compl. ¶ 100.) However, the Amended Complaint is devoid of any particularized facts—no internal reports, memoranda, or communications—suggesting Defendants were aware that the FDA would reject the NDA or that their public disclosures were false when made. *See In re Intelligroup*, 527 F. Supp. 2d at 286. Moreover, Plaintiffs also do not cite to any supposed "confidential witnesses" to support their claims—a fundamental deficiency that further undermines any inference of scienter. *See Rahman v. Kid Brands, Inc.*, Civ. No. 11-1624, 2012 WL 762311, at *14 (D.N.J. Mar. 8, 2012). The Third Circuit has deemed Plaintiffs' bald assertions that Defendants "must have known" an impermissible attempt to plead fraud by hindsight. *California Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 158 (3d Cir. 2004). For example, in *In re Columbia Laboratories*, the plaintiffs alleged that the defendant knowingly concealed that its clinical trial did not demonstrate efficacy because the results did not achieve a certain level of statistical significance and thus the FDA therefore was likely to reject its NDA. Civ. No. 12-614, 2013 WL 5719500, at *2–3 (D.N.J. Oct. 21, 2013), *aff'd*, 602 F. App'x 80. In a decision affirmed by the Third Circuit, the district court dismissed this theory of scienter, holding that the plaintiffs' allegations were "not supported by any factual particulars" and therefore amounted to nothing more than "must have known[s]." *Id*. at *6–7; *see also Sapir v. Averback*, Civ. No. 14-7331, 2016

WL 554581, at *10–14 (D.N.J. Feb. 10, 2016) (rejecting similar "must have" knowns). Accordingly, the Court finds that Plaintiffs have not sufficiently alleged scienter.

B. MOTION TO STRIKE ALLEGATIONS

Separately, Defendants seek to strike certain allegations from the Amended Complaint. Fed. R. Civ. P. Rule 12(f) allows the Court to strike from a pleading any insufficient defense or any immaterial, impertinent or scandalous matter. Motions to strike are generally disfavored by the Courts. *Larsen v. Pennsylvania*, 955 F. Supp. 1549, 1582 (M.D. Pa. 1997). "To prevail on a motion to strike, the movant must show that the allegations being challenged are so unrelated to Plaintiff's claims as to be unworthy of any consideration and that their presence in the pleadings will be prejudicial." *Flanagan v. Wyndham Int'l, Inc*., Civ. No. 02-237, 2003 WL 23198798, at *1 (D.V.I. Apr. 21, 2003). Such motions are not favored because they are a drastic remedy to be resorted to only when required for the purpose of justice. *Krisa v. The Equitable Life Assurance Soc'y*, 109 F. Supp. 2d 316, 319 (M.D.Pa. 2000). "In considering a motion to strike the Court will deem as admitted all of the non-moving party's well-pleaded facts, draw all reasonable inferences in the pleader's favor and resolve all doubts in favor of denying the motion." *Flanagan*, 2003 WL 23198798, at *1, (citing *Wailua Assocs. v. Aetna Cas. and Sur. Co*., 183 F.R.D. 550, 553-554 (D. Haw. 1998)).

"A motion to strike redundant, immaterial, impertinent or scandalous matter is also viewed with disfavor as 'a time waster.'" *Id.* (quoting *Somerset Pharm., Inc. v. Kimball,* 168. F.R.D. 69, 71 (M.D. Fl.1996)). The Court will not strike such matter unless it bears no possible relation to the dispute or could confuse the issues. *Id.* (citing *Government Guarantee Fund et al. v. Hyatt Corp.,* 166 F.R.D. 321, 324 (D.V.I.1996); *Delaware Health Care, Inc., v. MCD Holding Co.,* 893 F.Supp. 1279, 1291–92 (D. Del. 1995)). "Mere redundancy, immateriality, impertinence or

scandalousness is not sufficient to justify striking an allegation—the allegation must also be shown to be prejudicial to the moving party." *Id.* (citing *Hardin v. American Elec. Power,* 188 F.R.D. 509, 511 (S.D. Ind. 1999)). Scandalous matter does not merely offend someone's sensibilities; it must improperly cast a person or entity in a cruelly derogatory light. *Skadegaard v. Farrell,* 578 F.Supp. 1209, 1221 (D.N.J.1984).

Here, Defendants argue that the Amended Complaint "contains lengthy references to unadjudicated and irrelevant allegations from two separate lawsuits that bear no relationship to the claims and issues in this case. As a result, these allegations should be stricken." (Moving Br. at 39.) The Amended Complaint alleges that sales of Aquestive's former number one seller, Suboxone, had died down, and Aquestive sought different avenues to stay in business, leading Aquestive to put all of their efforts into Libervant. (Am. Compl. ¶¶ 26–35.) Aquestive was in competition with Neurelis, a San Diego company, to reach the market first. (Am. Compl. ¶¶ 104–07.) Both companies had obtained an orphan drug designation—Aquestive for Libervant, and Neurelis for its drug, Valtoco. (*Id.* ¶ 106.) However, "if Valtoco [was] approved first, Aquestive risk[ed] not being able to sell Libervant until 7 years later." (*Id.* ¶ 107.) According to Plaintiffs, Neurelis established a substantial lead in the race to approval which prompted Aquestive to become litigious. (*Id.* ¶¶ 107–31.) First, Aquestive "threatened to extort a waiver of Voltoco's impending orphan drug exclusivity." (*Id.* ¶ 120.) Then, "[o]n November 1, 2019, Aquestive filed a citizen petition with the FDA seeking that it stay approval of Valtoco until Neurelis completed an additional study." (*Id.* ¶ 131.) Plaintiffs reference Suboxone's sales decline and these other suits in an attempt to provide a basis and motivation for Defendants' subsequent, allegedly fraudulent actions.

Here, the Court concludes that "[s]uch allegations may or may not be borne out in discovery; they may or may not ultimately be found admissible in evidence on relevancy, Rule 403, hearsay, or other grounds. But [the Court] cannot conclude that the[se other suits] are so immaterial as to warrant their being struck." *Venson v. Pro Custom Solar LLC*, Civ. No. 19-19227, 2020 WL 6613214, at *3 (D.N.J. Nov. 12, 2020); *see e.g.*, *Gittens-Bridges v. City of New York*, Civ. No. 19-272, 2020 WL 3100213, at *7 (S.D.N.Y. June 11, 2020) (collecting cases for the proposition that evidence of past discriminatory practices of an employer is generally relevant in employment discrimination claims); *Greer v. Cty. of San Diego*, Civ. No. 19-0378, 2019 WL 5453955, at *14 (S.D. Cal. Oct. 24, 2019) (denying motion to strike allegations of prior litigation because the complaint "hinge[d] on showing a pattern of misconduct of which the County and individually named Defendants had notice."). Here, Plaintiffs' claim that the allegations concerning Suboxone sales decline and these other suits provide motive for Defendants' subsequent fraudulent actions. Insofar as Defendants have not shown that Plaintiffs' allegations are so unrelated to their claims as to be unworthy of any consideration, Defendants' motion to strike allegations will be DENIED.

IV. CONCLUSION

For the reasons stated above, the Court will GRANT Defendants' Motion to Dismiss without prejudice, but will DENY Defendants' Motion to Strike. Plaintiffs will be given leave to amend their Complaint to remedy the defects described herein within 30 days. Plaintiffs are cautioned that should the Second Amended Complaint again be found to fail to state a claim, that dismissal may be with prejudice. An appropriate Order will follow.

Date: **March 14, 2023**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE